August 13, 2025

Baisheng Medical Co., Ltd.
Kaimin Chen
RA Specialist
No.11, Fusheng Road, Xinhui District
Jiangmen
Guangdong, 529100
China

Re: K250841
Trade/Device Name: Electrotherapy Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: July 14, 2025
Received: July 14, 2025

Dear Kaimin Chen:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250841

Device Name
Electrotherapy Electrodes

Indications for Use *(Describe)*
Electrotherapy Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Electrotherapy Electrodes are intended to be used with marketed Electrical Stimulators, (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation)) for transmitting electrical current. The electrodes are for OTC (Over-The-Counter) or Prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

510(K) Number: K250841

I. GENERAL INFORMATION

Applicant:

Baisheng Medical Co., Ltd.

No.11,Fusheng Road,Xinhui District,Jiangmen,Guangdong.China. P.C:529100

Chen Xi

Tel : 86 - 0750 - 6628113

E - mail: renzheng@bs0750.com

Contact Person:

Chen Kaimin

Phone:+86-15626286758

E - mail: venus@bs0750.com

Date Prepared: Aug 13 ,2025

II. DEVICE INFORMATION

Trade Name: Electrotherapy Electrodes

Model : LBS-Φ2, LBS-Φ3, LBS-Φ5, LBS-Φ7, LBS-Φ9, LBS-2×2, LBS-4×4, LBS-5×5, LBS-2×3, LBS-5×3.5, LBS-6×4, LBS-6×5, LBS-8×4, LBS-9×6, LBS-10×7, LBS-12×8, LBS-12×10, LBS-8.5×5, LBS-12×7, LBS-15×5, LBS-Φ2L, LBS-Φ3L, LBS-Φ5L, LBS-Φ7L, LBS-Φ9L, LBS-2×2L, LBS-4×4L, LBS-5×5L, LBS-2×3L, LBS-5×3.5L, LBS-6×4L, LBS-6×5L, LBS-8×4L, LBS-9×6L, LBS-10×7L, LBS-12×8L, LBS-12×10L, LBS-8.5×5L, LBS-12×7L, LBS-15×5L

Common Name : Cutaneous Electrode

Classification Name: Cutaneous Electrode

Regulation Number: 21 CFR 882.1320

Regulatory Class: Class II

Product Code: GXY

Classification Panel :Neurology

Type of 510(k) submission: Traditional

PREDICATE DEVICE INFORMATION

PREDICATE DEVICE INFORMATION

Predicate device:

510(K) Number:K180865

Company Name: ZMI Electronics, Ltd.

Trade Name: ZMI Self-Adhesive Electrodes

Common Name: Cutaneous Electrode

Product Code: GXY

III. DEVICE DESCRIPTION

Electrotherapy Electrodes provide a means for establishing electrical contact between the lead connected to a TENS, EMS or NMES stimulation device and the skin, and are multi-layer, flexible structures composed of laminated materials commonly used in the application:

1st layer: Insulation material: Tan fabric

2nd layer: Double sides adhesive tape

3rd layer: Conductive film (Carbon Film)

4th layer: Self-adhesive conductive hydrogel

5th layer: Plastic release film

Connection: Leadwire/Snap button

The electrodes are designed for single-patient & single application use. Because of the adhesive nature of the conductive hydrogel, no securing materials are required to secure the device to the patient's skin.

IV. INDICATIONS FOR USE

Electrotherapy Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Electrotherapy Electrodes are intended to be used with marketed Electrical Stimulators, (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrodes are for OTC (Over-The-Counter) or Prescription use.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The following tables shows similarities and differences of use, design, and material between our device and the predicate devices.

Comparison to predicate device:

Description	Subject Device	Predicate Device	Comparison
510K Number	K250841	K180865	-
Product Code	GXY	GXY	SE
Proprietary Name	Cutaneous Electrode	Cutaneous Electrode	-
Manufacturer	Baisheng Medical Co., Ltd.	ZMI Electronics, Ltd.	-
Intended use	Electrotherapy Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Electrotherapy Electrodes are intended to be used with marketed Electrical Stimulators, (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrodes are for OTC (Over-The-Counter) or Prescription use.	ZMI Self-adhesive electrodes are intended for use as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current. The electrodes are for OTC (Over-The-Counter) or Prescription use.	SE

Target Population	Adult	Adult	SE
Design feature and material	Five layers: 1st layer: Insulation material: Tan fabric 2nd layer: Double sides adhesive tape 3rd layer: Conductive film (Carbon Film) 4th layer: Self-adhesive conductive hydrogel 5th layer: Plastic release film Connection: Leadwire/Snap button	Three layers: 1. Insulation backing material: Fabric/Foam/ Tan fabric 2. Conductive film: Aluminum foil film /Carbon film/Carbon film coated with silver/ 3. Conductive hydrogel	SE
Electrical Connection	Leadwire Snap button	Leadwire Snap button Magnetic button	SE
Lead Wire connector	Leadwire connector .080" (2mm) female socket connector	Leadwire connector .080" (2mm) female socket connector	SE
Non-sterile	Non-sterile	Non-sterile	SE
Disposable/ Reusable	Disposable	Reusable	-
Adhesive Type	Self-adhesive	Self-adhesive	SE
Environment of use	For OTC (Over-The-Counter) or Prescription use.	For OTC (Over-The-Counter) or Prescription use.	SE
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993	SE
Single Patient Use	Yes	Yes	SE

Description	Subject Device	Predicate Device	Comparison
Shape	Rectangular, Round	Round, Rectangular, Square, Oval, and Butterfly	SE The shape and size are related to the treatment area. Smaller area may cause higher current density, which leads to discomfort and burns. The current densities for any shaped electrodes exceeding 2mA r.m.s /cm^2 may require the special attention of the user. The color is mainly for identification and marketing purpose, and does not raise any new concerns of safety or effectiveness.
Color	Tan	White, Red, Black, and Tan	
A.C. Impedance	≤ 160 ohms	<200 ohms	SE

Discussion:

Our device is essentially identical to the predicate device in terms of indication for use, design feature and material, electrical connection, labeling, adhesive type, environment of use, biocompatibility and A.C. Impedance. The minor differences do not raise any safety and effectiveness concerns.

VI. Summary of Non-Clinical Testing

Electrotherapy Electrodes are composed of Tan fabric, Double sided adhesive tape, Conductive film (Carbon Film), self-adhesive conductive hydrogel, Plastic release film, Leadwire/Snap button. Adhesive performance was evaluated by performing a skin adhesion test. Electrode stability was evaluated by assessing electrical performance under IFU normal use conditions.

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device.

- Electrical safety per IEC 60601-1
- IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, section 201.15.101.7
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems
- Shelf life

In addition to the available device-specific guidelines, we have developed a method to test the packaging labeling, product appearance, impedance, dimension, connection between electrode and electrode wire, the cross-sectional area of the electrode connection wire, wire length and plug insertion and unplugging force surrounding the Electrotherapy Electrodes.

Biocompatibility testing was performed to verify the equivalent safety of the materials that are used. According to ISO 10993-1:2018 , we evaluated and conducted the compatibility test for the proposed device. The following tests were identified and done.

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

All tests were verified to meet acceptance criteria.

VII. Clinical Test Conclusion

No clinical study is included in this submission

VIII. Conclusion

Verification testing of the Electrotherapy Electrodes included electrical and mechanical tests to show that it meets its target specifications over a range of operating and storage conditions. Verification and performance testing further demonstrated that it meets user needs as reflected in the functional specification.

The submitted Electrotherapy Electrodes have the same intended use and similar technological characteristics as the predicate devices. Moreover, information contained in the submission supplied demonstrates that any differences in their characteristics do not raise new concerns of safety or effectiveness. Thus, the submitted adhesive electrodes are substantially equivalent to the predicate devices.